PREVENTION

Reducing the risk of sexually transmitted infections in genitourinary medicine clinic patients: a systematic review and meta-analysis of behavioural interventions

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Objectives: Are behavioural interventions effective in reducing the rate of sexually transmitted infections (STIs) among genitourinary medicine (GUM) clinic patients?
Design: Systematic review and meta-analysis of published articles.
Data sources: Medline, CINAHL, Embase, PsychINFO, Applied Social Sciences Index and Abstracts, Cochrane Library Controlled Clinical Trials Register, National Research Register (1966 to January 2004).
Review methods: Randomised controlled trials of behavioural interventions in sexual health clinic patients were included if they reported change to STI rates or self reported sexual behaviour. Trial quality was assessed using the Jadad score and results pooled using random effects meta-analyses where outcomes were consistent across studies.
Results: 14 trials were included; 12 based in the United States. Experimental interventions were heterogeneous and most control interventions were more structured than typical UK care. Eight trials reported data on laboratory confirmed infections, of which four observed a greater reduction in their intervention groups (in two cases this result was statistically significant, $p < 0.05$). Seven trials reported consistent condom use, of which six observed a greater increase among their intervention subjects. Results for other measures of sexual behaviour were inconsistent. Success in reducing STIs was related to trial quality, use of social cognition models, and formative research in the target population. However, effectiveness was not related to intervention format or length.
Conclusions: While results were heterogeneous, several trials observed reductions in STI rates. The most effective interventions were developed through extensive formative research. These findings should encourage further research in the United Kingdom where new approaches to preventing STIs are urgently required.

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Recent reports highlight dramatic increases in sexually transmitted infections (STIs) in the United Kingdom[1][2] alongside substantial increases in sexual risk behaviour.[3] The government has responded with a national strategy for sexual health and HIV, which aims to improve the evidence base for prevention and sets targets for reducing new infections.[4][5] Increased infection rates have placed considerable pressure on genitourinary medicine (GUM) clinics,[3][6] which recorded over 1.5 million clinical episodes in England and Wales during 2002.[1] Re-infection and re-attendance are thought to be common, but are not identified in routine data. A survey in England estimated that 44% of those diagnosed with gonorrhoea during 1996 had previously attended a GUM clinic.[7] Reducing rates of re-infection among clinic patients by promoting behaviour change could contribute to current policy goals and improve public health.

We aimed to systematically review the evidence that behavioural interventions could reduce STIs in GUM clinic patients. A recent publication by the Health Development Agency[8] identified two high quality systematic reviews that considered randomised controlled trials (RCTs) of behavioural interventions in clinical settings that reported changes to STI rates.[9][10] Both observed considerable heterogeneity between trials and concluded that the effectiveness of interventions was related to their development through formative research. We sought to build upon this previous work using a systematic approach to identify trials, an explicit approach to appraising trial validity, and quantitative methods to explore possible sources of heterogeneity.[11][12] We also sought to broaden the scope of existing reviews by considering measures of sexual behaviour change, relating these to infection risk.

METHODS

Identification of trials

We searched seven databases of completed and ongoing research during January 2004 with no date or language restrictions (Medline, CINAHL, Embase, PsychINFO, Applied Social Sciences Index and Abstracts, Cochrane Library Controlled Clinical Trials Register, and the National Research Register). Searches used terms describing sexually transmitted infections or sexual behaviour combined (AND) with terms for prevention, health promotion, behavioural interventions, counselling, and psychological therapies. A full version of this report is available online.[12]

Inclusion and exclusion criteria

We included RCTs of behavioural interventions that aimed to reduce the risk of STIs in patients attending GUM or equivalent clinics.[12] Infection rates were the primary outcome of interest, but we also included trials describing changes to self reported sexual behaviour. We excluded trials that provided educational materials alone, or reported only knowledge, attitudes, or behavioural intentions. Two reviewers independently assessed trials for inclusion using a standardised form.[12]

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Abbreviations: GUM, genitourinary medicine; ITT, intention to treat; MD, mean difference; RCTs, randomised controlled trials; RR, relative risk

Trial quality

Two reviewers independently assessed trial quality using a standardised form based on the Jadad scoring system.[12 13] This considers the adequacy of randomisation, concealment, masking, completeness of follow up, and the use of intention to treat (ITT) analyses.

Data abstraction and analysis

All data were abstracted using a standardised form.[12] STI diagnoses were ascertained from laboratory or clinic records, or the results of screening visits. Sexual behaviour change was ascertained from self completed questionnaires or interviews. Dichotomous outcomes were expressed as relative risks (RR) while results for continuous outcomes were expressed as the differences between intervention and control groups' mean within-subject change from baseline (mean difference, MD).[12 14] For infection related outcomes and sexual risk behaviours, a RR less than 1 or a negative MD indicates a lower rate of infections or risk taking in the intervention group relative to control. In contrast, for protective behaviours a RR greater than 1 or a positive MD indicates greater adoption of the protective behaviour in the intervention group relative to control. Infection related outcomes were analysed as ITT while behavioural outcomes represent on-treatment analyses (in many cases no information was reported on those lost to follow up).

Where outcome data were consistently available across studies, results were pooled using random effects meta-analyses (Review Manager, version 4.2, Cochrane Collaboration, 2003). Heterogeneity was explored with stratified meta-analyses using covariates defined a priori (study population, intervention characteristics, and trial quality).[12]

RESULTS
Search for trials
We included 31 papers reporting 14 trials (identified by principal citation, fig 1).[12] Most rejected RCTs did not recruit patients from a relevant setting. Initial agreement on inclusion was good ($\kappa = 0.70$) with disagreements resolved by discussion.

Study characteristics
Population and setting
Most trials were conducted in the United States (table 1). Two trials recruited over 60% of all participants.[15 16] Four trials recruited only males[17–20] and three only females.[21–23] Three trials focused on adolescents or young women.[21 23 26] Most trials restricted entry to those with a recently diagnosed STI,[17 18 20–25 27] and/or reporting high risk sexual behaviours.[16 18 26] The largest trial did not restrict entry on these grounds and reported a 32% baseline STI rate.[15]

Trial quality

Jadad scores were low ($\leqslant 3$ out of 5) reflecting an expected lack of masking and limited descriptions of trial methods.[17 21 26–28] Recruitment, adherence, and follow up rates were low (weighted mean 45% n = 12, 66% n = 10, and 69% n = 12), especially for interventions lasting over two sessions. Recruitment was greatest for small group interventions. Five trials reported differential follow up rates,[17 18 23 24 26] though
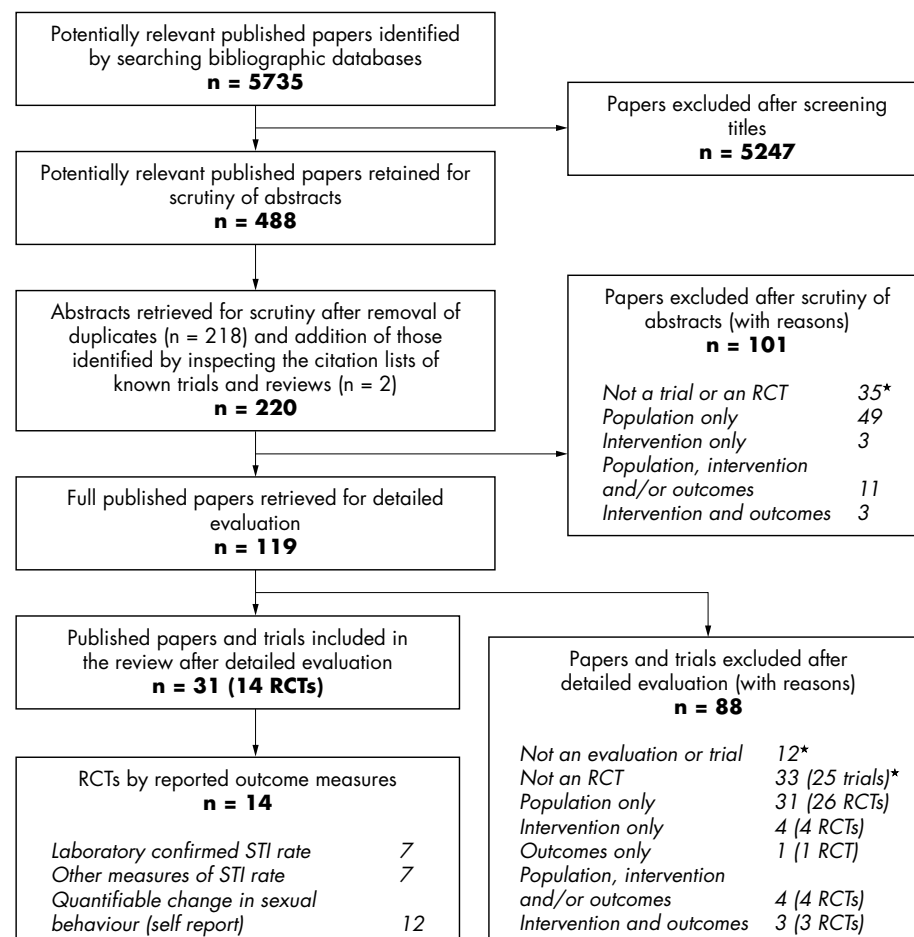

Figure 1 Flow of trials included and excluded from this review. (*No further details reported on those papers or trials not reporting evaluations or RCTs.)

Potentially relevant published papers identified by searching bibliographic databases
n = 5735

Papers excluded after screening titles
n = 5247

Potentially relevant published papers retained for scrutiny of abstracts
n = 488

Abstracts retrieved for scrutiny after removal of duplicates (n = 218) and addition of those identified by inspecting the citation lists of known trials and reviews (n = 2)
n = 220

Papers excluded after scrutiny of abstracts (with reasons)
n = 101

Not a trial or an RCT	*35**
Population only	*49*
Intervention only	*3*
Population, intervention and/or outcomes	*11*
Intervention and outcomes	*3*

Full published papers retrieved for detailed evaluation
n = 119

Published papers and trials included in the review after detailed evaluation
n = 31 (14 RCTs)

Papers and trials excluded after detailed evaluation (with reasons)
n = 88

Not an evaluation or trial	*12**
Not an RCT	*33 (25 trials)**
Population only	*31 (26 RCTs)*
Intervention only	*4 (4 RCTs)*
Outcomes only	*1 (1 RCT)*
Population, intervention and/or outcomes	*4 (4 RCTs)*
Intervention and outcomes	*3 (3 RCTs)*

RCTs by reported outcome measures
n = 14

Laboratory confirmed STI rate	*7*
Other measures of STI rate	*7*
Quantifiable change in sexual behaviour (self report)	*12*

Table 1 Characteristics of included trials

Trial location and dates	Population*	Number recruited (% female)	Age of participants (years)	Follow up	Intervention length and format	Trial quality Jadad score	Recruitment rate	Adherence rate	Follow up rate (at end point)
Balmer, 1998[17] Nairobi, Kenya (trial dates not stated)	Men with current STI	240 (0%)	Not reported	6 months	26×60 minutes weekly small group sessions	0	Not stated	Not stated	93% intervention; 44% control
Boyer, 1997[24] San Francisco, USA, Jan 1992 to Jan 1993	Heterosexual men and women (46% African American, 15% Hispanic) with current (39%) or previous STI (61%)	399 (49%)	42% <25	5 months	4×60 minutes weekly individual sessions	3	38%	48%	66% intervention; 49% control
Branson, 1998[25] Houston, USA, March 1992 to June 1993	Heterosexual men and women (90% black) with history of STI (48% current STI)	964 (43%)	35% >29; 19% <20	12 months	4 small group sessions in 2 weeks plus 1 at 2 months	3	59%	47%	73% any, and 22% complete follow up
Imrie, 2001[18] London, UK, Sept 1995 to Nov 1997	Homosexual men (91% white) with acute STI and/or history of unprotected intercourse and/or concerns about sexual practices	343 (0%)	23% >34; Median 29 (range 18–58)	12 months	One 7 hour group workshop	3	72%	71%	66% intervention; 78% control
Kalichman, 1999[19] Atlanta, USA (trial dates not stated)	African American heterosexual men	117 (0%)	Mean 33 (range 18–50)	6 months	2×180 minutes small group sessions	2	Approx. 70%	85%	69% (reportedly similar between groups)
Kamb, 1998[15] Five US clinics, July 1993 to Sept 1996	Heterosexual men and women (32% current STI)	5758 (43%)	Not reported (all >14)	12 months	1×20 minutes and 3×60 minutes (enhanced) or 2×20 minute (brief) individual sessions	2	43%	72%	66% (reportedly similar between groups)
Maher, 2003[20] Miami, USA, Sept 1994 to Dec 1995	Black men with confirmed/probable STI	581 (0%)	Mean 24 (range 16–29)	12 months	1×60 min and 2×40–50 minutes sessions in 30 days	2	92%	46% attended ≥2 sessions	Not applicable
Metzler, 2000[26] Oregon, USA (trial dates not stated)	Male and female adolescents (68% white) reporting recent high-risk sexual activity	339 (68%)	Mean 18 (males) 17 (females)	6 months	5×60–90 minute individual sessions	1	37%	68% attended ≥4 sessions	53% intervention
National Institute of Mental Health (NIMH), 1998[16] 37 US clinics, Jan 1994 to Sept 1996	Men and women (74% African American, 25% Hispanic) reporting recent high risk sexual activity	2426† (42%)	(32% <17) 25% <25	12 months	7 group sessions, initially twice weekly (1×60 minutes and 6×90–120 minutes)	3	33%	63% attended ≥6 sessions	76% intervention; 39% control
O'Leary, 1998[28] Seven US clinics (trial dates not stated)	Men and women (91% Black)	659 (41%)	Mean 30	3 months	7 group sessions totalling 10 hours	1	24%	Not stated	70% intervention; 74% control
Orr, 1996[21] Indiana, USA (trial dates not stated)	Female adolescents (55% black) with Chlamydia trachomatis infection	209 (100%)	Mean 18 (range 14–19)	6 months	1×10–20 minutes Individual session	0	Not stated	Not applicable	54% (reportedly similar between groups); 83% control
Shain, 1999[22] San Antonio, USA, Jan 1993 to July 1994	Heterosexual women with non-viral STI (68% Hispanic, 31% African American)	617 (100%)	Mean 22 (36% <19)	12 months	3×3–4 hour group sessions over 3 weeks	2	65%	82% attended ≥2 sessions	91% intervention
Shrier, 2001[23] Boston, USA, July 1996 to July 1998	Young women (49% black, 18% Hispanic) with cervicitis or pelvic inflammatory disease	123 (100%)	Median 17.5 (range 13–22)	12 months	1×30 minutes individual session	2	51%	95%	50% intervention; 87% control
Solomon, 1989[27] Boston, USA, 1986 (trial dates not stated)	Men and women (8.5% black) returning for "test of cure"	182 (20%)	Median 24 (range 18–73)	Not stated	One group session	1	73%	Not applicable	46% control; Not applicable

*The terms used to describe sexuality and ethnic groups reflect those used in the original papers.
†Results reported for the NIMH trial relate only to those recruited from sexual health clinics. This study also recruited women from community Health Service Organisations (total n=3706).[16]
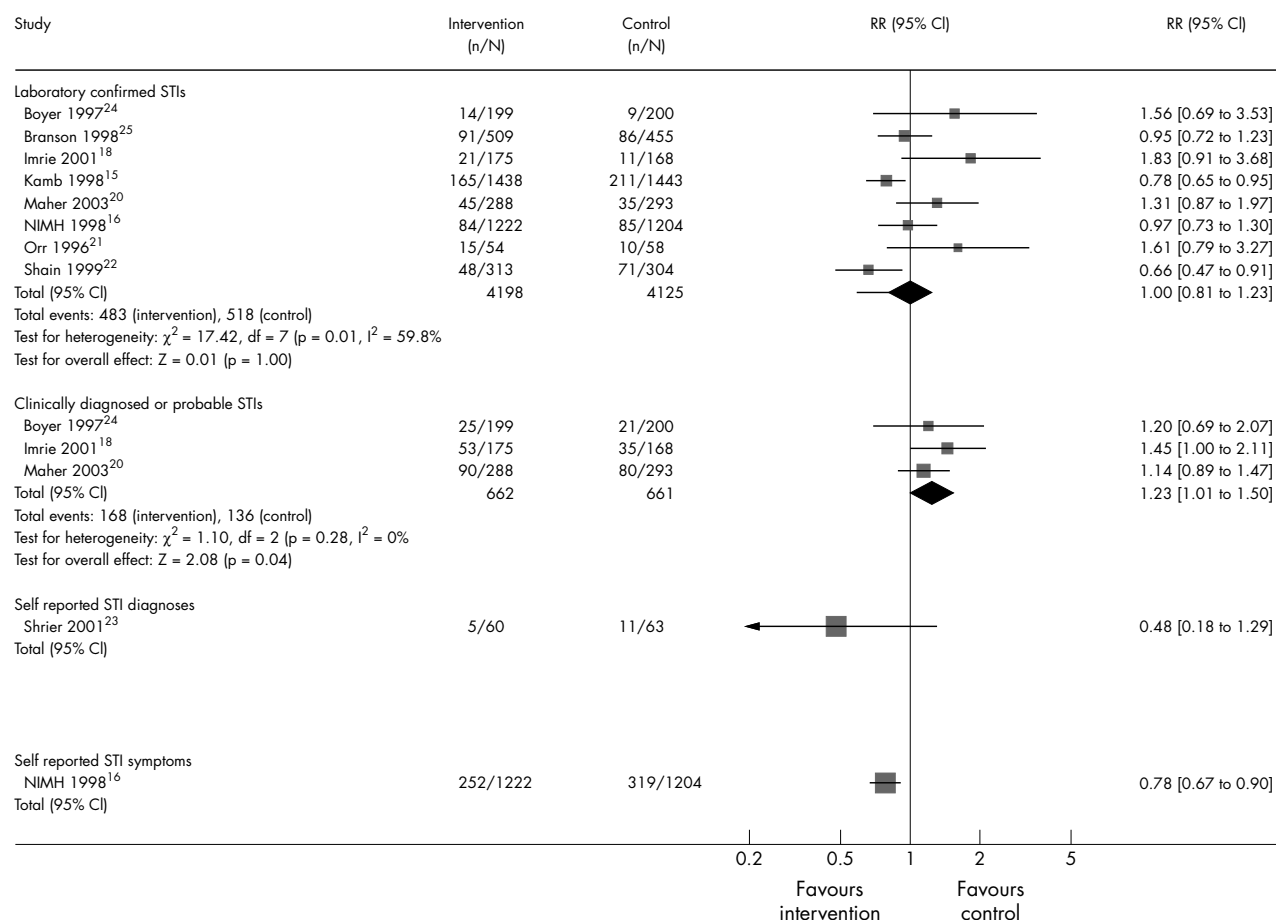
Study	Intervention (n/N)	Control (n/N)	RR (95% CI)	RR (95% CI)
Laboratory confirmed STIs				
Boyer 1997[24]	14/199	9/200		1.56 [0.69 to 3.53]
Branson 1998[25]	91/509	86/455		0.95 [0.72 to 1.23]
Imrie 2001[18]	21/175	11/168		1.83 [0.91 to 3.68]
Kamb 1998[15]	165/1438	211/1443		0.78 [0.65 to 0.95]
Maher 2003[20]	45/288	35/293		1.31 [0.87 to 1.97]
NIMH 1998[16]	84/1222	85/1204		0.97 [0.73 to 1.30]
Orr 1996[21]	15/54	10/58		1.61 [0.79 to 3.27]
Shain 1999[22]	48/313	71/304		0.66 [0.47 to 0.91]
Total (95% CI)	4198	4125		1.00 [0.81 to 1.23]

Total events: 483 (intervention), 518 (control)
Test for heterogeneity: $\chi^2 = 17.42$, df = 7 (p = 0.01, $I^2 = 59.8\%$)
Test for overall effect: Z = 0.01 (p = 1.00)

Clinically diagnosed or probable STIs				
Boyer 1997[24]	25/199	21/200		1.20 [0.69 to 2.07]
Imrie 2001[18]	53/175	35/168		1.45 [1.00 to 2.11]
Maher 2003[20]	90/288	80/293		1.14 [0.89 to 1.47]
Total (95% CI)	662	661		1.23 [1.01 to 1.50]

Total events: 168 (intervention), 136 (control)
Test for heterogeneity: $\chi^2 = 1.10$, df = 2 (p = 0.28, $I^2 = 0\%$
Test for overall effect: Z = 2.08 (p = 0.04)

Self reported STI diagnoses				
Shrier 2001[23]	5/60	11/63		0.48 [0.18 to 1.29]
Total (95% CI)				

Self reported STI symptoms				
NIMH 1998[16]	252/1222	319/1204		0.78 [0.67 to 0.90]
Total (95% CI)				

0.2 0.5 1 2 5
Favours intervention   Favours control

Figure 2 Results for laboratory confirmed STIs, clinically diagnosed STIs, self reported STIs, and self reported symptoms at trial end points. CI, confidence interval; n, number of events; N, number of participants; RR, relative risk. Laboratory confirmed STI includes gonorrhoea, chlamydia, syphilis, HIV, trichomonas (two trials[14 22]), non-specific urethritis (one trial[14]), chancroid and lymphogranuloma venereum (one trial[18]). Clinically diagnosed STIs also includes non-specific urethritis[16 18 22 23] or mucopurulent cervicitis,[22] pelvic inflammatory disease,[22 23] trichomonas,[22 23] first presentations of genital warts, herpes simplex, or hepatitis B infection,[16 23] scabies, or pediculosis pubis,[23] and presumptive treatment of either gonorrhoea or chlamydia on clinical grounds.[18 22] Results for the trial by Kamb relate to the enhanced intervention.[13] Equivalent results for the brief intervention are RR 0.82 (95% CI 0.68 to 0.99).

the group with greatest attrition was inconsistent. We labelled five trials as higher quality using a post hoc definition that required a Jadad score of two or three, masking of outcome assessors (seven trials), and non-differential follow up.[15 16 19 20 22]

Experimental and control interventions

Intervention format and length varied considerably (see table A on *STI* website www.stijournal.com/supplemental). One trial also compared an enhanced intervention with a brief one based on US best practice guidelines for individualised risk reduction counselling.[15 29 30] Most other US trials adapted these guidelines for their control interventions, which are more structured and detailed than usual care currently provided in UK GUM clinics.[12]

Experimental interventions explored many similar themes, including risk perception, barriers to safer sex, and triggers to unsafe sex. Individually based interventions concentrated on accepting and negotiating condom use[21 23] and personal goal setting,[15 20 24 26] using roleplay to develop skills.[20 24 26] In addition, group interventions explored self esteem in the context of social expectations[16 18 25] and increasing self efficacy.[16 22 28] Modelling behaviours and skills was an important aspect of many interventions.[16 17 19 22 25 28]

The two largest trials cited the theory of reasoned action and, less specifically, social cognition theory as the basis for

their interventions.[15 16] Social cognition theory asserts that attitudes to a behaviour, perceived support for that behaviour, and self efficacy determine intentions and subsequent actions.[31] Other investigators also cited cognitive models such as the health belief model[21] and AIDS risk reduction model,[22 24] which encourage participants to label themselves as vulnerable, commit to change, take action, and maintain change.[32] Three trials cited the information motivation behavioural skills model,[19 25 26] which asserts that personalised information, motivation, and behavioural skills are prerequisites of adopting protective behaviours.[31] Finally, two trials cited the transtheoretical model of behaviour change.[18 22] This represents change in terms of ordered stages allowing health promotion messages to be tailored to an individual's readiness to change.

Trial results and quantitative data synthesis
Laboratory confirmed STIs

Four out of nine trials considering this outcome observed a greater reduction in their intervention groups relative to controls,[15 16 22 25] a result that was statistically significant (p<0.05) for two.[15 22] Pooled results do not indicate an overall effect (RR 1.00 (95% confidence interval 0.81 to 1.23)). However, visual examination of the forest plot and statistical testing suggests heterogeneity between trials that prevents over-reliance on summary measures of effect (fig 2,
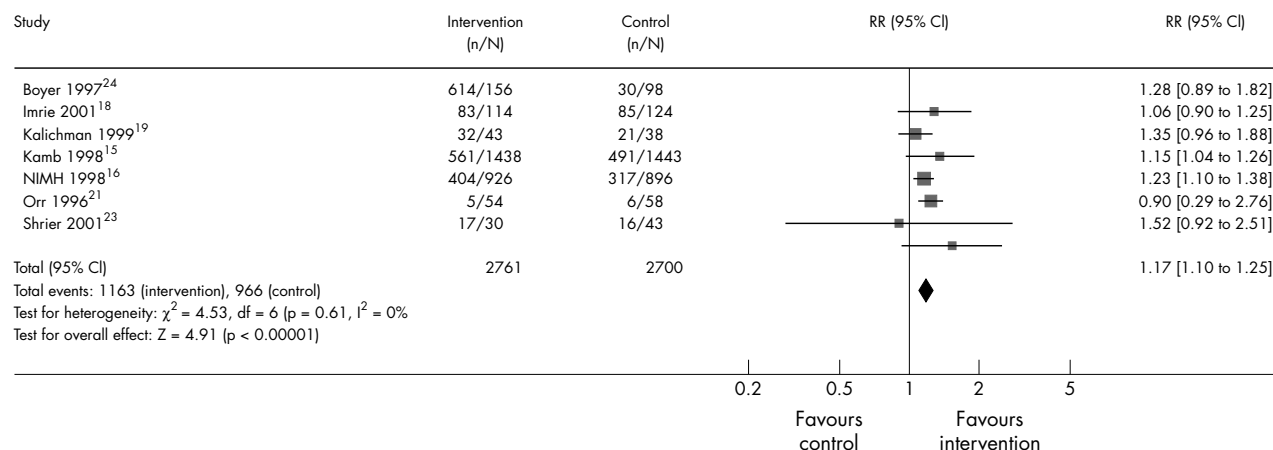
Study	Intervention (n/N)	Control (n/N)	RR (95% CI)	RR (95% CI)
Boyer 1997[24]	614/156	30/98		1.28 [0.89 to 1.82]
Imrie 2001[18]	83/114	85/124		1.06 [0.90 to 1.25]
Kalichman 1999[19]	32/43	21/38		1.35 [0.96 to 1.88]
Kamb 1998[15]	561/1438	491/1443		1.15 [1.04 to 1.26]
NIMH 1998[16]	404/926	317/896		1.23 [1.10 to 1.38]
Orr 1996[21]	5/54	6/58		0.90 [0.29 to 2.76]
Shrier 2001[23]	17/30	16/43		1.52 [0.92 to 2.51]
Total (95% CI)	2761	2700		1.17 [1.10 to 1.25]

Total events: 1163 (intervention), 966 (control)
Test for heterogeneity: $\chi^2 = 4.53$, df = 6 (p = 0.61, $I^2 = 0\%$)
Test for overall effect: Z = 4.91 (p < 0.00001)

0.2   0.5   1   2   5

Favours control   Favours intervention

Figure 3 Results for consistent condom use (condoms used (nearly) always or no unprotected sex) at trial end points. CI, confidence interval; n, number of events; N, number of participants; RR, relative risk. Outcomes refer to self reported sexual behaviour for the previous 1–12 months. Results for Imrie relate to the previous 1 month.[16] Equivalent results for 12 months were RR 1.23 (95% CI 0.93 to 1.62).

p = 0.001). In addition, a funnel plot of these results suggests evidence of publication bias (see fig A on *STI* website www.stijournal.com/supplemental, p = 0.003 Egger test). One further trial also reported a statistically significant effect on reducing gonorrhoea and urethral discharge, but did not present the original data (reported RRs 0.39 and 0.36).[17]

Trials reporting significant effects had among the greatest adherence and follow up rates.[15 22] Generally, high quality trials were more likely to report a protective effect, though pooled results were not significantly different (high quality RR 0.89 (0.70 to 1.12), low quality RR 1.29 (0.89 to 1.87)).[15 16 20 22] Pooled results for trials enrolling both sexes[15 16 24 25] (RR 0.90 (0.78 to 1.04)) or young women[21 22] (RR 0.97 (0.41 to 2.32)) were greater than results for the remaining trials.[18 20]

Intervention format or length was not associated with trial results (group based RR 0.94 (0.70 to 1.25) versus individually based RR 1.16 (0.76 to 1.75)). Similarly, Kamb found that both brief and enhanced interventions were equally effective when compared to a short information session.[15] We did find evidence that the theoretical basis of interventions was related to effectiveness, though differences in pooled results were not statistically significant (social cognition models RR 0.91 (0.71 to 1.16) versus other trials RR 1.19 (0.84 to 1.68)). In addition, extensive formative research, including interviews, focus groups, input from community representatives, and pilot testing, was reported by the four most effective trials.[15 16 22 25]

Clinically diagnosed STIs

Four studies considered clinically diagnosed STIs (fig 2). One trial found no reduction in any individual diagnosis[25] while others observed greater STI rates in their intervention groups compared to controls.[18 20 24] Pooling of these results suggests an overall effect (RR 1.23 (1.01 to 1.50)) and there was no evidence of statistical heterogeneity (p = 0.58).

Self reported STIs

Two trials considered self reported diagnoses and found no significant effects.[23 26] However, one trial observed an effect on self reported symptoms that was greater than that for laboratory confirmed infections.[16]

Self reported condom use

Six out of seven trials reporting consistent condom use (condoms always used or used at every sexual encounter)

observed a greater increase in their intervention groups than controls.[15 16 18 19 23 24] Examination of the forest plot and statistical testing do not indicate heterogeneity between trials (fig 3, p = 0.61) and the pooled result suggests an overall effect (RR 1.17 (1.10 to 1.25)). In contrast with laboratory confirmed infections, there is no evidence of publication bias (see fig B on *STI* website www.stijournal.com/supplemental, p = 0.98 Egger test).

Pooled results do not suggest that effects were related to trial quality (high quality RR 1.19 (1.11 to 1.28) *v* low quality RR 1.12 (0.97 to 1.29)), intervention format (group based RR 1.18 (1.05 to 1.33) *v* individually based RR 1.16 (1.06 to 1.28)), intervention length, the use of theory, or formative research. Results for trials recruiting females (RR 1.40 (0.88 to 2.20)) were greater than for trials recruiting mixed populations (RR 1.19 (1.10 to 1.27)) or males alone (RR 1.14 (0.92 to 1.42)).

Five trials considered the proportion of sexual encounters protected by condoms.[16 19 22 24 28] Two found increased rates in intervention subjects relative to controls (table 2). Other trials reported inconsistent effects on refusing unsafe sex[19 28] and using condoms with recent partners.[23 24]

Sexual partners

Five out of seven trials reported fewer sexual partners among their intervention groups relative to controls (table 2),[17 22 24 26 28] while two reported fewer partners among controls.[19 25] Two of these trials also reported a reduction in sexual encounters with strangers or non-monogamous partners,[26] and more avoidance of sex with partners suffering from known STIs.[22] However, another intervention had no effect on homosexual men reporting unprotected sex with a partner of different or unknown HIV status.[18]

DISCUSSION

Several trials of behavioural interventions in sexual health clinic patients observed a greater reduction in laboratory confirmed STIs among their intervention groups relative to controls despite using different intervention formats in different populations. Successful trials were larger and of higher quality than those reporting no reduction in infection rates, and the most effective interventions were based on social cognition or related theoretical models and developed through extensive periods of formative research. We also found evidence that behavioural interventions increase consistent condom use, though effects on other aspects of sexual behaviour were inconsistent. There was no evidence

Table 2 Results for behavioural outcomes at trial end points (excludes consistent condom use, fig 3)

Trial	Outcome	Time period	Intervention group n/N or mean difference (SD)	Control group n/N or mean difference (SD)	Effect size (95% CI)
Balmer, 1998[17] / Boyer, 1997[24]	Number of new sexual partners	Not stated	Paper reports NS reduction (absolute risk difference −0.6 per 100 person months), however data not shown		
	Proportion of sex acts protected by condoms	Entire study period (5 months)	−14.1% (47.7) N=121	−10.1% (47.3) N=133	MD −4.0% (−15.7 to 7.7)
	Sexual partners engaging in unprotected sex		−0.6 (SD not reported)	−0.4 (SD not reported)	MD −0.2 (paper reports p<0.05)
Branson, 1998[25]	Used condom with most recent sexual partner	Last 3 months	60/124	52/107	RR 1.00 (0.76 to 1.30)
	More than one sexual partner per month		32/124	24/107	RR 1.15 (0.73 to 1.83)
Imrie, 2001[18]	Most recent act of unprotected sex with partner of different/unknown HIV status	Entire study period (12 months)	15/31	18/39	RR 1.05 (0.64 to 1.72)
Kalichman, 1999[19]	Refused unsafe sex	Last 3 months	32/43	23/38	RR 1.23 (0.90 to 1.68)
	Acts of unprotected intercourse		−3.6 (12.1) N=43	−5.9 (29.2) N=38	MD −2.3 (−7.7 to 12.3)
	Proportion of sex acts protected by condoms		23.8% (32.2) N=43	21.3% (39.9) N=38	MD 2.5% (−12.1 to 17.1)
	Number of sexual partners		−0.8 (4.1) N=43	−2.8 (7.3) N=38	MD 2.0 (−0.1 to 4.1)
Metzler, 2000[26]	Frequency of intercourse and condom use Number of sexual partners and non-monogamous partners	Entire study period (6 months)	Paper reports significant (p<0.05) decrease in sexual partners, non-monogamous partners, and contacts with strangers in intervention group relative to control, however data and effect size not shown		
NIMH, 1998[16]	Sexual contacts with strangers Acts of unprotected intercourse	Last 3 months	−12.9 (47.6) N=926	−8.1 (58.8) N=896	MD −4.8 (−8.2 to −1.5)
	Proportion of sex acts protected by condoms		37.1% (34.4) N=926	26.1% (34.1) N=896	MD 11.0% (7.9 to 14.2)
O'Leary, 1998[28]	"Risky" sex acts	Entire study period (3 months)	−0.8 (11.1) N=292	−0.7 (9.3) N=180	MD −0.1 (−1.5 to 1.3)
	Proportion of sex acts protected by condoms		16.0% (44.0) N=292	17.0% (45.0) N=180	MD −1.0% (−9.3 to 7.3)
	Number of sexual partners		−1.1 (5.0) N=292	−0.5 (3.7) N=180	MD −0.6 (−1.2 to 0.0)
Orr, 1996[21]	Never uses condoms	Entire study period (6 months)	15/54	32/58	RR 0.50 (0.31 to 0.82)
	More than five acts of unprotected sex	Last 3 months	175/249	182/228	RR 0.88 (0.79 to 0.98)
Shain, 1999[22]	More than one sexual partner	Last 3 months	81/249	100/228	RR 0.74 (0.59 to 0.93)
	Avoiding sex with partner incompletely treated for STI or with STI symptoms		210/249	163/228	RR 1.18 (1.07 to 1.30)
Shrier, 2001[23]	Used a condom with most recent sexual partner	Entire study period (12 months)	18/30	18/34	RR 1.13 (0.74 to 1.74)
	Frequency of condom use		0.4 (SD not reported)	0.4 (SD not reported)	MD 0.1 (paper reports NS)
Solomon, 1989[27]	Redemption of condom coupons	Not stated	1.0 (0.6) N=89	0.8 (0.6) N=93	MD 0.2 (0.0 to 0.4)

CI, confidence interval; MD, mean difference; n, number of events; N, number of participants; NS, not statistically significant (p≥0.05); RR, relative risk; SD, standard deviation.

that an intervention's success in reducing infections or increasing consistent condom use was related to its format or length.

One trial observed no difference in effect between a multiple session enhanced intervention and a two session brief one.[15] This brief intervention was similar to the control intervention used by many trials,[20–22 24 25] including one that successfully reduced infection rates.[22] In effect, the control groups in these trials received an intervention that goes beyond current UK practice, making it difficult to generalise results or transfer effect estimates to a UK settings.

The quality of identified studies was frequently poor. Masking is difficult to achieve in trials of behavioural interventions, but we did consider masking of outcome assessors in our quality assessment as this may reduce bias.[33] We included only RCTs in this review, which could have resulted in the omission of potentially relevant information. However, a suitable unbiased control group is essential to avoid ascribing sexual behaviour change to the effects of the intervention rather than the diagnosis of an STI itself.[32 33] In addition, we found evidence of publication bias for the primary outcome (laboratory confirmed infections), though we attempted to identify all publicly funded research in the United Kingdom.

Two previous reviews also reported inconsistent results, though they suggest that adherence rates and the development of an intervention through formative research were predictors of success.[9 10] We identified five trials not included in these reviews,[17 20 23 26 28] four of which report infection related outcomes, yet our findings suggest similar factors are important to an intervention's effectiveness. Formative research seeks to identify the behaviours, motivations, and beliefs within the target population that lead to increased risk, and link these to the key elements of an intervention.[10 32] The format, setting, delivery, and acceptability of the intervention can then be explored through pilot testing.[32] Theory may provide a framework for this process, though models do not specify the inclusion of particular elements within an intervention, and we also found evidence that effective interventions were more likely to be based on theoretical models relating behaviour to individual cognitions.

Trials appeared more effective at increasing (consistent) condom use than reducing infections. This could represent a chance event, or bias resulting from the different methods of ascertainment. Alternatively, small changes in condom use may be an insensitive marker of overall STI risk, which is the sum of many behavioural factors.[10 32] At the population level, increased condom use has been accompanied by increases in other risky sexual activities and a marked rise in infections.[3] Further analysis of the NIMH trial data also suggests that the number of sexual partners remains an important risk factor for gonorrhoea infection regardless of changes to condom use.[34] However, too few trials reported both behavioural outcomes alongside infection rates to explore this issue further.

This review highlights a need for research on behavioural interventions in a UK setting, where new approaches to reducing infection rates are urgently required. Heterogeneity between trials for the primary outcome of interest means that we cannot rely on simple summary measures of effect, but there is evidence that interventions can successfully change sexual behaviour and reduce infection rates if appropriately developed and targeted to a population. The success of interventions appears unrelated to their intensity. This is important, as the number of sessions is likely to be a major factor in determining cost. However, even the briefest intervention shown to be effective could not be introduced into routine GUM practice without further investment in premises, staff, and training. Information on the likely effect size, acceptability, and cost effectiveness of introducing behavioural interventions into the United Kingdom will be critical to those developing new services. However, this information cannot be simply extrapolated from existing evidence, which mainly derives from the United States. We propose that future studies should develop their experimental interventions by tailoring the approaches shown to be most effective in US settings, and crucially inform this process by a period of formative research that incorporates qualitative approaches. While this is likely to be time consuming and costly, without such an approach any proposed intervention is unlikely to be successful.

CONTRIBUTORS

One supplementary table and two figures are on the *STI* website (www.stijournal.com/supplemental)

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